Sterility Testing of Parenteral & Ophthalmic Drug Products in Support of Your Sterility Assurance Program

Nelson Labs®
A Sotera Health company

Nelson Labs is a global provider of microbiological testing, analytical chemistry, and advisory services, supporting pharma, biopharma, and medical device companies. We have over 35 years of experience solving challenges that are not typically addressed in routine testing. We have the capabilities and capacity to perform any testing that you need to outsource to get your pharma or biopharma product to market. We are US FDA registered, cGMP compliant, and ISO 17025 accredited and have laboratories located throughout North America and Europe.

One of the essential testing demands in support of a sterility assurance or contamination control program for pharma and biopharma is a sterility test (test of/for sterility). To help ensure that we can accommodate our customers' requirements, Nelson Labs has added a new isolator line for sterility testing. Our new Skan isolator is state-of-the-art technology, helping to ensure the absence of any microbial contamination during a test and increasing testing capacity. The Skan isolator is the same or similar technology to what our pharma and biopharma customers will have in their manufacturing processes, increasing the likelihood of successful regulatory audit outcomes.

Nelson Labs offers isolators and cleanrooms to support sterility testing for parenteral and ophthalmic drug products. Information regarding the use of each platform is listed below.

- **Isolator**
  - Isolators are ideal for testing small-volume parenteral products and also for testing liquids via membrane filtration.
  - Regulatory agencies usually prefer isolators over cleanrooms.
  - Isolators reduce the likelihood of human error and especially of human contamination.
  - Isolators contribute to a higher level of operator safety.

- **Cleanroom**
  - There is more flexibility for capacity and volume.
  - Cleanrooms are better suited for manipulation of the drug product beyond simply expelling contents from a syringe.

Contact us today!

801-290-7500 | www.**nelsonlabs**.com | sales@nelsonlabs.com

US FDA registered and third-party accredited to ISO 17025 standards

